

PATENT
Attorney Docket No.: 10139/04302 (00276-06PUS1)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)
Schlienger et al.)
Serial No.: 10/590,125) Group Art Unit: 3733
Filed: June 4, 2007) Examiner: Steven J. Cotroneo
For: INTRAMEDULLARY NAIL) **Board of Patent Appeals and**
Confirmation No.: 4059) **Interferences**

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed October 12, 2011, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 12 - 24 in the Final Office Action dated July 13, 2011, as clarified in the Advisory Action mailed September 28, 2011. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Synthes USA, LLC which is a wholly owned subsidiary of Synthes, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1 - 11 and 25 have been canceled. Claims 12 - 24 have been rejected in the Final Office Action and are the subject of the present appeal.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

The following summary refers to the specification and identifies certain claim limitations with the reference characters of one or more drawings. The association in this summary of a claim limitation with a particular reference character, figure, or passage from the specification is only exemplary and is not intended to limit the scope of the claims.

The present invention describes, as recited in claim 12, an intramedullary nail 1. *Specification*, p. 4, ll. 18; Fig. 1. The intramedullary nail 1 comprises an elongated nail body having a proximal end 3, a distal end 2 for insertion into the medullary canal, a central axis 4 and

a total length L. *Id.* at p. 4, ll. 18 - 20; Fig. 1. The intramedullary nail 1 comprises three locking sections 5, 6, 7 along the length of the nail body between the proximal 3 and distal 2 ends. *Id.* at p. 4, l. 20; Fig. 1. Each locking section 5, 6, 7 includes a through-hole 8 for receiving a locking screw. *Id.* at p. 4, ll. 21 - 22; Fig. 1. The three locking sections include a proximal locking section 5, a medial isthmus locking section 7 and a distal locking section 6. *Id.* at p. 4, ll. 22 - 26; Figs. 1, 6. The intramedullary nail 1 comprises two distinct intermediate sections 9, 10 separating the three locking sections 5, 6, 7. *Id.* at p. 5, ll. 6 - 10; Fig. 1. The intermediate sections 9, 10 have fewer through-holes 8 per unit length than each of the three locking sections 5, 6, 7. *Id.* The locking section 5 nearest the proximal end 3 has a length L₅ forming an angle β with the intermediate section 9 adjacent the proximal locking section 5 where β is in the range of 7° < β < 13°. *Id.* at p. 5, ll. 13 - 16; Fig. 1. The locking section 5 nearest the proximal end 3 comprises an elongated through-hole 8. *Id.* at p. 4, ll. 22 - 23; Fig. 1. The isthmus locking section 7 includes a proximal through hole 8 and a distal through hole 8 where the proximal through hole 8 is arranged at an angle of 90° relative to the distal through hole 8. *Id.* at p. 4, ll. 25 - 26; Fig. 6.

The present invention describes, as recited in claim 23, an intramedullary nail 1. *Specification*, p. 4, ll. 18; Fig. 1. The intramedullary nail 1 comprises an elongated nail body having a proximal end 3, a distal end 2 for insertion into the medullary canal, a central axis 4, and a total length L. *Id.* at p. 4, ll. 18 - 20; Fig. 1. The intramedullary nail 1 comprises a proximal locking section 5, distal locking section 6, and isthmus locking section 7 spaced along the length of the nail body. *Id.* at p. 4, ll. 22 - 26; Figs. 1, 6. The proximal locking section 5 nearest the proximal end 3, the distal locking section 6 nearest the distal end 2, and the isthmus locking section 7 are located between the proximal 5 and distal 6 locking sections. *Id.* Each

locking section 5, 6, 7 includes a through-hole 8 for receiving a locking screw. *Id.* at p. 4, ll. 21 - 22; Fig. 1. The intramedullary nail 1 comprises a first intermediate section 9 separating the proximal 5 and isthmus 7 locking sections and a second intermediate section 10 separating the isthmus 7 and distal 6 locking sections. *Id.* at p. 5, ll. 6 - 10; Fig. 1. Each intermediate section 9, 10 has fewer through-holes 8 per unit length than the locking sections 5, 6, 7. *Id.* The proximal locking section 5 forms an angle β with the first intermediate section 9, where β is in the range of $7^\circ < \beta < 13^\circ$. *Id.* at p. 5, ll. 13 - 16; Fig. 1. The proximal locking section 5 comprises an elongated through-hole 8. *Id.* at p. 4, ll. 22 - 23; Fig. 1. The isthmus locking section 7 includes a proximal through hole 8 and a distal through hole 8 where the proximal through hole 8 is arranged at an angle of 90° relative to the distal through hole 8. *Id.* at p. 4, ll. 25 - 26; Fig. 6.

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 12 - 24 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,766,174 to Perry in view of U.S. Patent No. 5,041,115 to Frigg et al. (hereinafter “Frigg”) in further view of WO 00/06039 corresponding to U.S. Patent No. 6,547,791 to Buhren et al. (hereinafter “Buhren”) and U.S. Patent No. 6,270,499 to Leu et al. (hereinafter “Leu”).

7. Argument

- I. The Rejection of Claims 12 - 24 Under 35 U.S.C. § 103(a) as Obvious over Perry in view of Frigg in further view of Buhren and Leu Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 12 - 24 under 35 U.S.C. § 103(a) as being obvious over Perry, Frigg, Buhren, and Leu. *7/13/11 Office Action*, p. 2.

- B. The Cited References Do Not Disclose or Suggest
Wherein the Isthmus Locking Section Includes a
Proximal Through Hole and a Distal Through Hole,
the Proximal Through Hole Being Arranged at an
Angle of 90° relative to the Distal Through Hole, as
Recited in Claim 12

Claim 12 recites, in relevant part, an intramedullary nail “wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole.” The Examiner acknowledges that Perry, Frigg, and Buhren do not disclose an isthmus locking section including two through holes arranged at a relative angle A as recited. *7/13/11 Office Action*, p. 5. The Examiner attempts to cure this deficiency with Leu.

It is respectfully submitted that the Examiner’s assertion that the bores 7 and the anteroposterior bore 29 being disposed on a portion of the intramedullary nail 1 of Leu being analogous to the recited isthmus locking section of claim 12 is misplaced. As would be clear to those skilled in the art, an isthmus locking section of an intramedullary nail is a portion of the nail which, when implanted to a desired location, is located within the isthmus of the bone - i.e., the thin shaft extending between the enlarged ends of the bone. Those skilled in the art understand that fractures in this area require different treatment than those on the trochanteric area and that portions of a nail extending within the isthmus will be subjected to different forces and, therefore, have specific structural requirements that distinguish isthmian portions of nails from the ends which reside outside the isthmus. In its entirety, Leu neither states nor suggests that the bores 7, 29 are located at the isthmus of the bone. In contrast, as illustrated in Fig. 1 and the annotated Fig. 1 provided by the Examiner, the bores 7, 29 are within the thickened trochanter at the proximal end of the bone – outside of the isthmus. Specifically, Leu states that

the bores 7 are “in the area of the proximal end 3” of the nail. *Leu*, col. 3, line 57. As the bore 29 is between the bores 7, it is also in the area of the proximal end 3. Furthermore, Leu states that a “preferred refinement” of the invention consists of a bore running across the central axis of the nail “in the area of the proximal end” to lock the nail in position. *Id.* at col. 2, lines 63 - 67.

The intramedullary nail 1 of Leu is described as functioning as an intramedullary angle plate providing increased contact between the implant and bone to permit reconstruction of the head of the tibia even if that tibia is osteoporotic. *Id.*, col. 2, ll. 40 - 53. Specifically, the head 10 of the nail at the proximal end is required to lock the nail in position even where bone quality is low. Thus, the bores 7 and 29 are provided not in the isthmus, but in the thickened end of the bone to increase bony purchase as the head 10 of the nail 1 provides the load-bearing element. *Id.* at col. 2, ll. 54 - 67. In addition, Leu shows the nail 1 including bores 6 and a threaded bore 8 at the *distal end* of the nail 1 to be disposed near the isthmus of the bone, not for a *medial* locking section. *Id.* at Figs. 1, 4, 6. As described in the specification, these bores are located “in the area of the distal end” of the nail. *Id.* at col. 2, ll. 63 - 67. Thus, it is respectfully submitted that Leu does not disclose or suggest an isthmus locking section and, accordingly, through holes thereof.

Furthermore, even if the bores 7, 29 were considered through holes of an isthmus locking section (which is not conceded), Leu fails to disclose or suggest an isthmus locking section including “a proximal through hole and a distal through hole, the proximal through hole being *arranged at an angle of 90° relative to the distal through hole*,” as recited in claim 12. It is noted that claim 12 recites that the two through holes are arranged at a specific angle of 90°, not a relative angle with respect to each other such as any non-parallel orientation. In contrast, Leu

only teaches bores 7 and an anteroposterior bore 29 extending through the intramedullary nail 1 that are arranged in a non-parallel fashion, but includes absolutely no showing or suggestion that any of these bores is perpendicular to any other. *Leu*, col. 3, ll. 57-62; Figs. 1, 4, 6. In its entirety, *Leu* includes no disclosure with respect to the angles of these bores relative to one another. The Examiner also states that it should have been obvious to achieve the recited angular relationship by trial and error. However, it is respectfully submitted that the Examiner's assertion is unsupported by the disclosure of *Leu* which does not indicate the specific 90° orientation and that the Examiner's assertion is based instead on impermissible hindsight. Thus, it is respectfully submitted that no conclusion about the angular relationship between the bores may properly be drawn from an examination of the drawings alone and that *Leu* does not cure the deficiencies of Perry, Frigg and Buhren.

Thus, it is respectfully submitted that Perry, Frigg, Buhren, and *Leu*, taken either alone or in any combination, do not disclose or suggest the above recitation of claim 12 and that claim 12 is therefore in condition for allowance. Because claims 13 - 22 depend from and, therefore, include the limitations of claim 12, it is respectfully submitted that these claims are also allowable.

Claim 23 recites limitations substantially similar to claim 12, including an intramedullary nail "wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole." It is therefore respectfully submitted that Perry, Frigg, Buhren, and *Leu*, taken either alone or in combination, do not disclose or suggest the above recitation of claim 23 for substantially the same reasons noted above with respect to claim 12. Accordingly, it is respectfully submitted that

claim 23 is also in condition for allowance. Because claim 24 depends from and, therefore, includes the limitations of claim 23, it is respectfully submitted that this claim is also allowable.

C. The Perry Reference Is Incapable of Being Modified by any of the other Cited References with a Reasonable Expectation of Success

The Examiner also states that arguments against the references individually cannot show non-obviousness. The Examiner further states that the medial holes of Perry is being modified with the features of Leu. *7/13/11 Office Action*, p. 7. However, it is respectfully submitted that one skilled in the art would not have a reasonable expectation of success from the purported modification. Among other criteria, an obviousness argument requires that there be a reasonable expectation of success. *MPEP 2143.02*. The previous arguments clearly show that the bores 7, 29 of Leu relate to a different area of the bone (that is not the isthmus). Therefore, in view of these arguments, it is respectfully submitted that one skilled in the art would not have a reasonable expectation of success for the purported modification in view of the disclosure of Leu.

Furthermore, it is respectfully submitted that the Examiner's assertion that the device of Perry is capable of being modified with any teaching regarding an isthmus locking section having through holes arranged in any configuration other than parallel is also incorrect. The purported isthmus locking section of Perry comprises only bone transfixation holes 34a, 34b formed parallel to one another and no indication is provided in any of the references why this arrangement should be modified, much less modified as claimed. *Perry*, col. 3, ll. 10-19, 33-40; col. 5, ll. 43-53; Figs. 1 - 6. Perry is incapable of being modified to overcome this deficiency since the device of Perry is explicitly configured with parallel transfixation holes 32a, 32b, 34a, 34b so that insertion of a locating screw 28 into an indent 59 formed in anvil assembly 26 aligns

the guides holes 40a, 40b, 42a, 42b of the alignment tower 24 with respective transfixation holes 32a, 32b, 34a, 34b of the intramedullary nail 20. *Id.*, col. 3, ll. 33-40; col. 5, l. 40 - col. 6, l. 2; Figs. 1 - 3. It is therefore respectfully submitted that Perry teaches only one possible configuration of the alignment tower 24 with respect to the intramedullary nail 20 (*i.e.*, the configuration assumed when the locating screw 28 is received in the indent 59). Accordingly, the transfixation holes 34a and 34b of Perry which purportedly correspond to the through holes of the isthmus locking section of claim 12 can be disposed only in the disclosed parallel configuration. A primary focus in Perry is to provide a definitive means for locating the transfixation holes through the proper alignment thereof for the introduction of transfixation screws. Therefore, to provide the transfixation holes 34a and 34b in a non-parallel configuration teaches away from the device disclosed in Perry as the alignment feature with the tower 24 and the side bar 25 is no longer viable. Thus, a non-parallel transfixation hole 34a or 34b would find no utility in the device of Perry since there would be no means for locating the hole within the bone. It is unclear how any of the cited references would be adapted for Perry with regard to the 90° orientation when a primary focus in Perry is to provide a definitive means for locating the transfixation holes through the proper alignment thereof for the introduction of transfixation screws specifically with the described components therein. It is respectfully submitted that Perry is incapable of being modified to overcome this limitation.

Thus, it is respectfully submitted that independent claims 12 and 23 and dependent claims 13 - 22 and 24 are allowable for least these further reasons and are in condition for allowance.

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8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner and indicate that claims 12 - 24 are allowable.

Respectfully submitted,

Date:

Dec. 5, 2011

By:

Oleg F. Kaplun (Reg. No. 45,559)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276

CLAIMS APPENDIX

1-11. (Canceled)

12. (Previously Presented) An intramedullary nail comprising:

an elongated nail body having a proximal end, a distal end for insertion into the medullary canal, a central axis and a total length L;

three locking sections along the length of the nail body between the proximal and distal ends, each locking section including a through-hole for receiving a locking screw, the three locking sections including a proximal locking section, a medial isthmus locking section and a distal locking section; and

two distinct intermediate sections separating the three locking sections, the intermediate sections having fewer through-holes per unit length than each of the three locking sections,

wherein the locking section nearest the proximal end has a length L_s forming an angle β with the intermediate section adjacent the proximal locking section where β is in the range of $7^\circ < \beta < 13^\circ$,

wherein the locking section nearest the proximal end comprises an elongated through-hole; and

wherein the isthmus locking section includes a proximal through hole and a distal through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole.

13. (Previously Presented) The intramedullary nail of claim 12, wherein the intermediate sections have no through-holes

14. (Previously Presented) The intramedullary nail of claim 12, wherein:

the proximal locking section extends from the proximal end toward the distal end over a length L_5 , where $0.22 L < L_5 < 0.28 L$, and has a distal boundary;

the distal locking section extends from the distal end toward the proximal end over a length L_6 , where $0.18 L < L_6 < 0.22 L$, and has a proximal boundary; and

the isthmus locking section is located between the distal and proximal locking sections, and has a proximal boundary, a distal boundary and a length L_7 where $0.08 L < L_7 < 0.15 L$.

15. (Previously Presented) The intramedullary nail of claim 14, wherein the proximal boundary of the isthmus locking section is spaced a distance L_9 from the distal boundary of the proximal locking section, where $0.27 L < L_9 < 0.33 L$.

16. (Previously Presented) The intramedullary nail of claim 14, wherein the distal boundary of the isthmus locking section is spaced a distance L_{10} from the proximal boundary of the distal locking section, where $0.13 L < L_{10} < 0.30 L$.

17. (Previously Presented) The intramedullary nail of claim 16, where $0.32 L < (L_{10} + L_6) < 0.50 L$.

18. (Previously Presented) The intramedullary nail of claim 14, wherein the first intermediate section has a length L_9 between the proximal locking section and the isthmus locking section, and the first intermediate section has no through holes.

19. (Previously Presented) The intramedullary nail of claim 18, wherein the second intermediate section has a length L_{10} between the distal locking section and the isthmus locking section, and the second intermediate section has no through holes.

20. (Previously Presented) The intramedullary nail of claim 12, wherein the proximal through hole of the isthmus locking section is parallel to the elongated through hole of the proximal section.

21. (Previously Presented) The intramedullary nail of claim 12, wherein the through hole located nearest to the distal end is spaced a distance L_D to the distal end, where $0.01 L < L_D < 0.38 L$.

22. (Previously Presented) The intramedullary nail of claim 12, wherein the through hole located nearest to the proximal end is spaced a distance L_P to the proximal end, where $0.01 L < L_P <$

0.70 L.

23. (Previously Presented) An intramedullary nail comprising:

an elongated nail body having a proximal end, a distal end for insertion into the medullary canal, a central axis and a total length L;

a proximal locking section, distal locking section, and isthmus locking section spaced along the length of the nail body, the proximal locking section nearest the proximal end, the distal locking section nearest the distal end, and the isthmus locking section located between the proximal and distal locking sections, and each locking section including a through-hole for receiving a locking screw;

a first intermediate section separating the proximal and isthmus locking sections, and a second intermediate section separating the isthmus and distal locking sections, each intermediate sections having fewer through-holes per unit length than the locking sections,

wherein the proximal locking section forms an angle β with the first intermediate section, where β is in the range of $7^\circ < \beta < 13^\circ$,

wherein the proximal locking section comprises an elongated through-hole, and

wherein the isthmus locking section includes a proximal through hole and a distal

through hole, the proximal through hole being arranged at an angle of 90° relative to the distal through hole.

24. (Previously Presented) The intramedullary nail of claim 23, wherein the intermediate sections have no through-holes.

25. (Cancelled)

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.